MEMORANDUM

EPA File Symbol: 432-IEE Delta 5.0% WP

DP Barcode: D224609

Chemical: 97805 Deltamethrin

Test Materials: K Othrine WP 5
ref. no. 27 Y 1205,
4.95% deltamethrin,
is a beige powder

Decis 5% WP (inhalation and sensitization studies only)
ref. no. 12 Y 0315,
5.1% deltamethrin,
is a white powder.

From: Lawrence A. Fried, Biologist
Precautionary Review Section
Registration Support Branch (7505W)
Registration Division

7-29-96

To: George LaRocca, Product Manager, Team 13
John Hebert, Team Reviewer, Team 13

Applicant: 432 Agrevo Environmental Health

Performing Lab: Roussel UCLAF
102/111 Route de Noisy
93230 Romainville, France

Stillmeadow Inc. (inhalation and dermal sensitization only)
9525 Town Park Drive
Houston, Texas 77036

FORMULATION FROM LABEL

Ingredient(s)	% by wt.
Deltamethrin	5.0
Inerts	95.0
Total	100.0

BACKGROUND

AgrEvo Environmental Health has submitted acute oral toxicity (438888-04), acute dermal toxicity (439460-01), acute inhalation toxicity (438888-05), primary eye (439460-02), dermal irritation (438888-06) and dermal sensitization (438888-07) studies on Delta 5.0% WP. The primary review of these studies was performed by the California Department of Pesticide Regulation. The secondary review was performed by PRS.

RECOMMENDATION

81-1. Acute Oral: Category IV. The submitted study is acceptable.

81-2. Acute Dermal: Category IV. The submitted study is acceptable.

81-3. Acute Inhalation: Category IV. The submitted study is acceptable.

The California Department of Pesticide Regulation stated that "Analytical results and calculations used to determine the analytical exposure were not included in the report. The study is upgradeable if this information is submitted." PRS contacted the performing lab, Stillmeadow, Inc., and the analytical results and calculations were submitted to PRS (attached). PRS concludes that the additional data is satisfactory; therefore, the acute inhalation study (Lab no. 7210-90) is acceptable.

81-4. Eye Irritation: Category III. The submitted study is acceptable.

81-5. Dermal Irritation: Category IV. The submitted study is acceptable.

81-6. Dermal Sensitization: The test material did not elicit a dermal sensitization reaction under conditions of the test.

LABEL RECOMMENDATIONS: (generated by the PRS Label Review System)

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

ACUTE TOX ONE-LINER

ID No.: 432-IEE Delta 5.0% WP
DP Barcode: D224609
Chemical: 97805 Deltamethrin
Applicant: 432 AgrEvo Environmental Health
Test Materials: K Othrine WP 5 ref. no. 27 Y 1205, Deltamethrin, 4.95% (w/w), is a beige powder and Decis 5% WP (inhalation and sensitization studies only), ref. no. 12 Y 0315, 5.1% deltamethrin, is a white powder.
Date: July 30, 1996

Study, Animal, Test Laboratory, Study #, Date	MRID No.	Results	Tox. Cat.	Core Grade
Acute Oral, Rat, Roussel UCLAF, France, 91/2437/TX, 09-09-91	438888-04	LD_{50}>5000 mg/kg	IV	A
Acute Dermal, Rabbit, Roussel UCLAF, France, 91/2438/TX, 09/09/91	439460-01	LD_{50}>5000 mg/kg	IV	A
Acute Inhalation, Rat, Stillmeadow, Inc., Texas, 7210-90, 11-19-90	438888-05	LC_{50} >7.75 mg/L	IV	A
Eye Irritation, Rabbit, Roussel UCLAF, France, 91/2439/TX, 09/09/91	439460-02	Iridal involvement and corneal opacity cleared on day-3.	III	A
Dermal Irritation, Rabbit, Roussel UCLAF, France, 91/2488/TX, 09/09/91	438888-06	No irritation observed.	IV	A
Dermal Sensitization, Guinea Pig, Stillmeadow, Inc., Texas, 7211-90, 11-14-90	438888-07	Not a dermal sensitizer in guinea pigs	-	A

A = Acceptable

TO: Ann Prichard, Program Specialist
Pesticide Registration Branch

FROM: Medical Toxicology Branch

Date: May 28, 1996

PRODUCT REGISTRATION RECOMMENDATION SHEET

Formulated Product Name: Delta 5.0% WP
Chemical Code #: 3010
SB 950 #: Not assigned
ID #: EPA-160695-E
Document #: 51846-091
EPA #: 43888-822 (432-IEE)
Company Name: AgrEvo Environmental Health

RECOMMENDATION:

Submitted as Additional Data in conjunction with the EPA/CDPR Sharing Project.

The data reviewed are adequate to make a complete acute toxicological evaluation of the subject product.

All potential hazards associated with the use of the subject product, as indicated by the data reviewed, are adequately identified on the product label.

Registration is recommended.

Note: Deltamethrin is a high priority for risk assessment. Registration will not be possible until that assessment has been completed.

Charles Kahn
Associate Pesticide Review Scientist

5/30/96
Date

Staff Toxicologist

5-31-96
Date

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TO--File: Registration **Program Specialist:** Ann Prichard
Branch: Registration
FROM--Medical Toxicology

DATA PACKAGE SUMMARY AND RECOMMENDATION SHEET

Active Ingredient: Deltamethrin
Formulated Product Name: Delta 5.0% WP
Formulation: 5.00% Deltamethrin and 95.00% Inert ingredients
Chemical Code #: 3010
SB 950 #: Not assigned **ID #:** EPA-160695-E
Document #: 51846-091
EPA #: 43888-822
Company Name: AgrEvo Environmental Health

SUMMARY: ("One-liners" from each study worksheet,significant information not mentioned in worksheets, other pertinent information for ongoing review or registration. Attach additional sheets if needed)

The differences in formulation between DECIS 5% WP, K OTHRINE WP 5 and the subject product are of minimal toxicological concern. Therefore, the acute toxicity data is bridgeable to subject product.

DECIS 5% WP AND K OTHRINE WP 5 Acute Toxicity Categories

Acute Oral LD50	IV
Acute Dermal LD50	IV
Acute Inhalation LC50	Study Not Acceptable*
Eye Irritation	III
Dermal Irritation	IV

* See Conclusions

DECIS 5% WP AND K OTHRINE WP 5 A Acute Toxicity Studies

Acute Oral LD50
51846-091; 147058; Acute Oral LD50; 811; rat; Toxicology Department - Division Scientific ROUSSEL UCLAF, ROMAINVILLE - FRANCE; 9/9/91; Laboratory Study Number 91/2437/TX; (MRID 438888-04); K OTHRINE WP 5 (Beige powder); oral dose of 5000 mg/kg (administered in distilled water); 5/sex/dose; mortalities (M) 0/5 and (F) 0/5; clinical observations- slightly arched back and diarrhea; normal weight gain; necropsy- normal; LD50 > 5000 mg/kg; Toxicity Category IV; study acceptable. (Kahn, 5/22/96)

Acute Dermal LD50
51846-091; 147059; Acute Dermal; LD50; 812; rabbit; Departement de Toxicologie - Division Scientifique ROUSSEL UCLAF, ROMAINVILLE - FRANCE; 9/9/91; Laboratory Study Number 91/2438/TX; (MRID 439460-01); K OTHRINE WP 5 (Beige powder); dermal dose of 5000 mg/kg (premoistened with distilled water); 5/sex /dose; 24 hour exposure period (semi-occluded); mortalities (M) 0/5 and (F) 0/5, clinical observations- slight erythema; body weight gain normal; necropsy- no abnormalities noted; LD50 > 5000 mg/kg; Toxicity Category IV; study acceptable.(Kahn, 5/23/96)

Acute Inhalation LC50
51846-091; 147060; Acute Inhalation LD50; 813; rat; STILLMEADOW, Inc., Sugar Land, TX; 11/19/90; Laboratory Study Number: 7210-90; (MRID 438888-05); DECIS 5% WP REFERENCE: 12 Y 0315 11/06/90 (5.1% Deltamethrin - a white powder); inhalation dose of 7.75 mg/l (Analytical Value) and 14.7 mg/l (Nominal Value); 5/sex/dose; 4 hour exposure; MMAD+GSD 3.194+2.645 µm; mortalities: (M) 0/5 and (F) 0/5; clinical observations- activity decrease, lacrimation, nasal discharge, piloerection and salivation; necropsy- no observable abnormalities; reported LC50 > 7.75 mg/kg; Toxicity Category not determined; study not accepted but upgradeable upon submission of Analytical Results and the Calculations used to to determine the Analytical Exposure Concentration. (Kahn, 5/24/96)

Eye Irritation
51846-091; 147061; Eye Irritation; 814; rabbit; Departement de Toxicologie - Division Scientifique ROUSSEL UCLAF, ROMAINVILLE - FRANCE; 9/9/91; Laboratory Study Number 91/2439/TX; (MRID 439460-02); K OTHRINE WP 5 (4.95% Deltamethrin - a Beige powder); dosed with 100 mg/eye; 6 rabbit eyes tested; mortalities- 0/6; at Day 1 post-dose -Grade 2 (4/6), -1 (2/6) corneal opacity, -Grade 1 (3/6) iritis, -Grade 3 (1/6), -2 (4/6), -1 (1/6) conjunctival irritation; at day 3 post-dose -No eye irritation; Toxicity Category III; study acceptable. (Kahn, 5/28/96)

Dermal Irritation
51846-091; 147062; Dermal Irritation; 815; rabbit; Departement de Toxicologie - Division Scientifique ROUSSEL UCLAF, ROMAINVILLE - FRANCE; 9/9/91; Laboratory Study Number 91/2488/TX; (MRID 438888-06); K OTHRINE WP 5 (4.95% Deltamethrin - a Beige powder); 0.5 g/site; 4 hour exposure period (semi-occluded - test material moistened with distilled water); mortalities- 0/6; at 24, 48 and 72 hours post patch removal no skin irritation; Toxicity Category IV; study acceptable. (Kahn, 4/28/96)

CONCLUSIONS: **Do data support registration, if applicable? For formulated product, do data support registration of product as labelled?**

The submitted DECIS 5% WP and K OTHRINE WP 5 Acute Toxicity Studies have been reviewed and all the studies are acceptable, except the DECIS 5% WP acute inhalation toxicity study.

The DECIS 5% WP acute inhalation toxicity study that has been reviewed and found unacceptable could be upgraded to an acceptable study upon submission of the analytical data and calculations used to determine the concentration of the test material used in the study.

The subject product is to be used in formulating other products and is not being used as a spray. Possible inhalation exposure is minimal. Therefore, an acute inhalation toxicity study on the subject product is not being required at this time.

RECOMMENDATIONS: **What type of registration action is being requested? In case of ongoing registration, register or do not register? What other specific studies or data are requested?**

Submitted as Additional Data in conjunction with the EPA/CDPR Sharing Project.

The data reviewed are adequate to make a complete acute toxicological evaluation of the subject product.

All potential hazards associated with the use of the subject product, as indicated by the data reviewed, are adequately identified on the product label.

Registration is recommended.

Note: Deltamethrin is a high priority for risk assessment. Registration will not be possible until that assessment has been completed.

Charles Kahn
Associate Pesticide Review Scientist

5/30/96
Date

Staff Toxicologist

5-31-96
Date

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CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

DEPARTMENT OF PESTICIDE REGULATION

MEDICAL TOXICOLOGY BRANCH

TOXICOLOGY STUDY EVALUATION WORKSHEET
(acute and special studies)

I. STUDY IDENTIFICATION

Active Ingredient: Deltamethrin
Formulated Product Name: K OTHRINE WP 5
Chemical Code #: 3010
SB 950 #: Not assigned
Document #: 51846-091
EPA #: NA
ID: EPA-160696-E
Record #: 147058
Study Type: 811 - Acute Oral Toxicity
Full Study Title: Acute oral toxicity study of K OTHRINE WP 5 in the Rat
Company Sponsor: "AGROVET" ROUSSEL UCLAF
Conducting Laboratory Toxicology Department - Division Scientific ROUSSEL UCLAF, ROMAINVILLE - FRANCE
Report Date: September 9, 1991
Study Interval: March 21, 1991 to April 4, 1991

II. SUMMARY OF WORKSHEET

A. STUDY STATUS: Is report complete? No
Is study acceptable? Yes

- \- Meets EPA guidelines
- Yes Minor variances from guidelines
- \- Major variances from guidelines
- \- Could be upgraded with additional information (see VI-A)

- Yes Has useful data
- \- Insufficient data
- \- Non EPA validated study
- Other_____

B. CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?: No **If so, in what area?** NA

C. ONE LINER-One or two sentence summary of the study:
51846-091; 147058; Acute Oral LD50; 811; rat; Toxicology Department - Division Scientific ROUSSEL UCLAF, ROMAINVILLE - FRANCE; 9/9/91; Laboratory Study Number 91/2437/TX; (MRID 438888-04); K OTHRINE WP 5 (Beige powder); oral dose of 5000 mg/kg (administered in distilled water); 5/sex/dose; mortalities (M) 0/5 and (F) 0/5; clinical observations- slightly arched back and diarrhea; normal weight gain; necropsy- normal; LD50 > 5000 mg/kg; Toxicity Category IV; study acceptable. (Kahn, 5/22/96)

D. ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)? Yes

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Charles Kahn
Associate Pesticide Review Scientist

5/30/96
Date

Staff Toxicologist

5-31-96
Date

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:
Species: Rat
Strain: OFA Sprague-Dawley,
Source of animals: IFFA-CREDO Breeding Centre, FRANCE
Age at start: 35 days of age [Weighing (M) 110-122 g and (F) 115-121 g]
Route of administration: Gavage
Vehicle: Distilled water
Period of treatment: Single dose

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

	Units (mg/kg)
	5000
# Male Rats:	5
# Female Rats:	5

	Mortality
# Dead Male Rats:	0
# Dead Female Rats:	0

IV. STUDY DESIGN AND EVALUATION

A. TEST PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).
1. Test article: K OTHRINE WP 5 (Beige powder)
* 2. Analysis of dosing material: Administered in distilled water, no analysis of dosing material performed
3. Animal selection: OK
4. Animal husbandry: Housed by sex in groups of 5 - Temperature 22±2°C and Relative Humidity 30-70%
5. Mortality: See III-C
6. Number of animals: See III-C
* 7. Randomization of animals: Not reported
8. Dose level selection: OK
9. Route of administration: OK
10. Exposure conditions: OK
11. Controls: OK
12. Observations: Observed for mortality or other signs of gross toxicity frequently on day of dosing and at least once/day for 14 days post-dose.
13. Necropsies: OK
14. Appropriateness of methods: OK
15. Treatment of results: OK
16. Test report: OK
17. Consistency: OK
18. Good Laboratory Practice: OK
19. Other: OK

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

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V. RESULTS

A. EFFECTS REPORTED:
Mortalities (M) 0/5 and (F) 0/5. Clinical observations- slight arched back and diarrhea. Normal weight gain. Necropsy- normal.

B. ACUTE TOXICITY VALUE(LD50,LC50,etc):
LD50 > 5000 mg/kg

C. TOXICITY CATEGORY:
IV

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). None **What are they and can they be corrected with additional information?** NA **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? No **Are there any recommendations specific to this study?** NA

California ENVIRONMENTAL PROTECTION AGENCY

DEPARTMENT OF PESTICIDE REGULATION

MEDICAL TOXICOLOGY BRANCH

TOXICOLOGY STUDY EVALUATION WORKSHEET
(acute and special studies)

I. STUDY IDENTIFICATION

Active Ingredient: Deltamethrin
Formulated Product Name: K OTHRINE WP 5
Chemical Code #: 3010
SB 950 #: Not assigned
Document #: 51846-091
EPA #: NA
ID: EPA-160696-E
Record #: 147059
Study Type: 812 - Acute Dermal Toxicity
Full Study Title: Acute Dermal Toxicity Study of K OTHRINE WP 5 in the Rabbit
Company Sponsor: "AGROVET" ROUSSEL UCLAF
Conducting Laboratory: Departement de Toxicologie - Division Scientifique ROUSSEL UCLAF, ROMAINVILLE - FRANCE
Report Date: September 9, 1991
Study Interval: March 26, 1991 to April 9, 1991

II. SUMMARY OF WORKSHEET

A. **STUDY STATUS: Is report complete?** No
Is study acceptable? Yes

- \- Meets EPA guidelines
- Yes Minor variances from guidelines
- \- Major variances from guidelines
- \- Could be upgraded with additional information (see VI-A)

- Yes Has useful data
- \- Insufficient data
- \- Non EPA validated study
- Other_____

B. **CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?:** No **If so, in what area?** NA

C. **ONE LINER-One or two sentence summary of the study:**
51846-091; 147059; Acute Dermal; LD50; 812; rabbit; Departement de Toxicologie - Division Scientifique ROUSSEL UCLAF, ROMAINVILLE - FRANCE; 9/9/91; Laboratory Study Number 91/2438/TX; (MRID 439460-01); K OTHRINE WP 5 (Beige powder); dermal dose of 5000 mg/kg (premoistened with distilled water); 5/sex/dose; 24 hour exposure period (semi-occluded); mortalities (M) 0/5 and (F) 0/5, clinical observations- slight erythema; body weight gain normal; necropsy- no abnormalities noted; LD50 > 5000 mg/kg; Toxicity Category IV; study acceptable.(Kahn, 5/23/96)

D. **ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?** No

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Charles Kahn
Associate Pesticide Review Scientist

5/30/96
Date

Staff Toxicologist

5-31-96
Date

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Rabbit
Strain: Albino Hyrid New Zealand White
Source of animals: Elevage Scientifique des Dombes, Chalaronne, FRANCE
Age at start: 2.5 months (Weight (M) 2.46-2.70 kg and (F) 2.43- 2.60 kg)
Route of administration: Dermal (semi-occluded)
Vehicle: Test material moistened with distilled water
Period of treatment: Single (24 hour exposure)

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

	Units (mg/kg)
	5000
# Male Rabbits:	5
# Female Rabbits:	5

	Mortality
# Dead Male Rabbits:	0
# Dead Female Rabbits:	0

IV. STUDY DESIGN AND EVALUATION

A. TEST PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** K OTHRINE WP 5 (Beige powder)
2. **Analysis of dosing material:** Used as received (moistened with distilled water)
3. **Animal selection:** OK
4. **Animal husbandry:** Individually housed in suspended, stainless steel cages with mesh floors - Temperature 19±3°C and Relative Humidity 30-70%
5. **Mortality:** See III-C
6. **Number of animals:** See III-C
* 7. **Randomization of animals:** Not reported
8. **Dose level selection:** OK
9. **Route of administration:** OK
10. **Exposure conditions:** OK
11. **Controls:** OK
12. **Observations:** Observed for mortality or other signs of gross toxicity frequently on day of dosing and once daily thereafter for 14 days
13. **Necropsies:** Gross necropsies all animals
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** OK
19. **Other:** OK

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED:
Mortalities (M) 0/5 and (F) 0/5. Clinical observations- slight erythema. Body weight gain -normal. Necropsy- no abnormalites noted.

B. ACUTE TOXICITY VALUE(LD50, LC50, etc):
LD50 > 5000 mg/kg

C. TOXICITY CATEGORY:
IV

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). None **What are they and can they be corrected with additional information?** NA **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? No **Are there any recommendations specific to this study?**
No

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'CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
MEDICAL TOXICOLOGY BRANCH
TOXICOLOGY STUDY EVALUATION WORKSHEET
(acute and special studies)

I.STUDY IDENTIFICATION

Active Ingredient: Deltamethrin
Formulated Product Name: DECIS 5% WP REFERENCE: 12 Y 0315 1/06/90
Chemical Code #: 3010
SB 950 #: Not assigned **ID:** EPA-160696-E
Document #: 51846-091 **Record #:** 147060
EPA #: NA
Study Type: 813 - Acute Inhalation LC50
Full Study Title: ACUTE INHALATION TOXICITY STUDY IN RATS WITH DECIS 5 % WP REFERENCE: 12 Y 0315 - RBC Study No. RBT-90-118
Company Sponsor: AgrEvo Environmental Health
Conducting Laboratory STILLMEADOW, Inc., Sugar Land, TX
Report Date: November 19, 1990
Study Interval: September 7, 1990 to September 21, 1990

II. SUMMARY OF WORKSHEET

A. **STUDY STATUS: Is report complete?** No
Is study acceptable? No

- \- **Meets EPA guidelines**
- \- **Minor variances from guidelines**
- Yes **Major variances from guidelines**
- Yes **Could be upgraded with additional information (see VI-A)**

Yes **Has useful data**
- \- **Insufficient data**
- \- **Non EPA validated study**

Other_____

B. **CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?** No **If so, in what area?** NA

C. **ONE LINER-One or two sentence summary of the study:**
51846-091; 147060; Acute Inhalation LD50; 813; rat; STILLMEADOW, Inc., Sugar Land, TX; 11/19/90; Laboratory Study Number: 7210-90; (MRID 438888-05); DECIS 5% WP REFERENCE: 12 Y 0315 11/06/90 (5.1% Deltamethrin - a white powder); inhalation dose of 7.75 mg/l (Analytical Value) and 14.7 mg/l (Nominal Value); 5/sex/dose; 4 hour exposure; MMAD+GSD 3.194+2.645 µm; mortalities: (M) 0/5 and (F) 0/5; clinical observations- activity decrease, lacrimation, nasal discharge, piloerection and salivation; necropsy- no observable abnormalities; reported LC50 > 7.75 mg/kg; Toxicity Category not determined; study not accepted but upgradeable upon submission of Analytical Results and the Calculations used to to determine the Analytical Exposure Concentration. (Kahn, 5/24/96)

D. **ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?** No

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Charles Kahn
Associate Pesticide Review Scientist

5/30/96
Date

Staff Toxicologist

5-31-96
Date

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Rat
Strain: HSD:(SD)
Source of animals: Harlan Sprague-Dawley, Inc., Houston, TX
Age at start: Young adults [Weighing (M) 278-311 g and (F),213-239 g]
Route of administration: Inhalation
Vehicle: None reported
Period of treatment: Single (4 hour exposure period)

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

	Units (mg/l)*
	7.75
# Male Rats:	5
# Females Rats:	5
	Mortality
# Dead Males Rats:	0
# Dead Females Rats:	0

* Analytical Value
Nominal Value 14.7 mg/l
MMAD ± GSD 3.194±2.645 µm

IV. STUDY DESIGN AND EVALUATION

A. TEST PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** DECIS 5% WP REFERENCE: 12 Y 0315 11/06/90 (5.1% Deltamethrin - a white powder)
* 2. **Analysis of dosing material:** Deficient; analytical data and calculations used to determine the exposure concentration were not detailed in the report.
3. **Animal selection:** OK
4. **Animal husbandry:** Housed 1-3 (by sex) per suspended, wire bottom, stainless steel cages
5. **Mortality:** See III C
6. **Number of animals:** See III C
* 7. **Randomization of animals:** Not reported
8. **Dose level selection:** OK
9. **Route of administration:** OK
10. **Exposure conditions:** OK
11. **Controls:** OK
12. **Observations:** Observed for mortality or other signs of gross toxicity the day of exposure and at least once daily thereafter for 14 days.
13. **Necropsies:** OK
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** OK
19. **Other:** NA

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED:
Mortalities: (M) 0/5 and (F) 0/5. Clinical observations- activity decrease, lacrimation, nasal discharge, piloerection and salivation. Necropsy- no observable abnormalities.

B. ACUTE TOXICITY VALUE(LD50,LC50,etc):
Reported LC50 > 7.75 mg/kg

C. TOXICITY CATEGORY:
Not determined - study not accepted

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). What are they and can they be corrected with additional information? Be specific:
Analytical results and calculations used to determine the analytical exposure were not included in the report. Study is upgradeable if this information is submitted.

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? No **Are there any recommendations specific to this study?** No

STILLMEADOW
INCORPORATED

Moses-
Pull this & put in our file copy. Do NOT Copy.

FAX TRANSMISSION COVER PAGE

Date: 26 Jul 96

To:
Name: Larry Fried
Company: U.S.E.P.A.
Fax No 703-308-8369
Subject: Standard Curve for Calculating Inhalation Concentration

From:
Name: Mark S. Holbert
Time Sent: 3:09

Pages Transmitted (Cover Page Included) 2

Additional Instructions This is calculation for Inhalation chamber Conc. for the Stillmeadow Study 7210-90 "Decis 5% WP". If you have any questions Please call. Thanks Mark

FAX: (713) 240-8448 Phone: (713) 240-8828

IF ALL PAGES INDICATED ON THIS COVER SHEET ARE NOT RECEIVED. PLEASE NOTIFY STILLMEADOW, INC., AS SOON AS POSSIBLE

multifactor calculation from Appendix "A" * $\frac{10\text{ml solvent}}{(2.5\text{min sample})(\text{Rate } 0.5\text{L/min})} = 8.00$

12852 Park One Drive ▮ Sugar Land Texas 77478 ▮ 713 240-8828 ▮ Fax 713 240-8448

ACUTE INHALATION TOXICITY STUDY IN RATS
Analytical Concentration Calculations
Test Material: DECIS 5 % WP REFERENCE: 12 Y 0315

Standard Curve

Standard	Conc. (mg/ml)	Mean Height
A	5.033	54237
B	4.026	42784
C	3.020	32196
D	2.013	21620
E	1.007	10738
F	0.5033	5416
G	0.2516	3950

Corr (r) = 0.99970 y intercept = 423.1 slope = 10595

Calculation for 7.75 Concentration

Sample Number	Peak Height	Conc. (mg/mL)	Multi. X Factor*	Chamber Conc. (mg/L)
1	15812.5	1.4525 x	8.00	11.62
2	6981.5	0.61905 x	8.00	4.952
3	8835.0	0.79395 x	8.00	6.352

* - Multiplication factor (mL/L) calculated from figures in Appendix A.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

DEPARTMENT OF PESTICIDE REGULATION

MEDICAL TOXICOLOGY BRANCH

TOXICOLOGY STUDY EVALUATION WORKSHEET
(acute and special studies)

I. STUDY IDENTIFICATION

Active Ingredient: Deltamethrin
Formulated Product Name: K OTHRINE WP 5
Chemical Code #: 3010
SB 950 #: Not assigned
Document #: 51846-091
EPA #: NA
ID: EPA-160696-E
Record#: 147062
Study Type: 815 - Dermal Irritation
Full Study Title: Primary Dermal Irritation Study of K OTHRINE WP 5 in the Rabbit
Company Sponsor: "AGROVET" ROUSSEL UCLAF
Conducting Laboratory: Departement de Toxicologie - Division Scientifique ROUSSEL UCLAF, ROMAINVILLE - FRANCE
Report Date: September 9, 1991
Study Interval: March 12, 1991 to March 15, 1991

II. SUMMARY OF WORKSHEET

A. STUDY STATUS: Is report complete? No
Is study acceptable? Yes

- Meets EPA guidelines
Yes Minor variances from guidelines
- Major variances from guidelines
- Could be upgraded with additional information (see VI-A)

Yes Has useful data
- Insufficient data
- Non EPA validated study
Other_____

B. CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?: No If so, in what area? NA

C. ONE LINER-One or two sentence summary of the study:
51846-091; 147062; Dermal Irritation; 815; rabbit; Departement de Toxicologie - Division Scientifique ROUSSEL UCLAF, ROMAINVILLE - FRANCE; 9/9/91; Laboratory Study Number 91/2488/TX; (MRID 438888-06); K OTHRINE WP 5 (4.95% Deltamethrin - a Beige powder); 0.5 g/site; 4 hour exposure period (semi-occluded - test material moistened with distilled water); mortalities- 0/6; at 24, 48 and 72 hours post patch removal no skin irritation; Toxicity Category IV; study acceptable. (Kahn, 4/28/96)

D. ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)? Yes

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Charles Kahn
Associate Pesticide Review Scientist

5/30/96
Date

Staff Toxicologist

5-31-96
Date

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Rabbit
Strain: Albino Hybrid New Zealand White
Source of animals: Elevage Scientifique des Domes, France
Age at start: 3 months of age (Weight 2.39 to 2.82 kg)
Route of administration: Dermal (semi-occluded)
Vehicle: 500 mg of test material was moistened with 0.5 ml of distilled water
Period of treatment: Single (4 hour exposure - semi-occluded)

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

	500 mg/site
# Rabbits:	6

	Mortality
# Dead Rabbits:	0

IV. STUDY DESIGN AND EVALUATION

A. TEST PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** K OTHRINE WP 5 (4.95% Deltamethrin - a Beige powder)
2. **Analysis of dosing material:** Dosed as received (moistened with - 0.5 ml distilled water/0.5 g of test material)
3. **Animal selection:** OK
4. **Animal husbandry:** Individually housed in suspended, stainless steel cages with mesh floors - Temperature 19±3°C and Relative Humidity 30-70%
5. **Mortality:** See III-C
6. **Number of animals:** See III-C
* 7. **Randomization of animals:** Not reported
8. **Dose level selection:** OK
9. **Route of administration:** OK
10. **Exposure conditions:** OK
11. **Controls:** OK
12. **Observations:** Observed for skin irritation at 30 to 60 minutes, 24, 48 and 72 hours post patch removal.
13. **Necropsies:** Not required
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** OK
19. **Other:** OK

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED:
Mortalities- 0/6. At 24, 48 and 72 hours post patch removal no skin irritation.

B. ACUTE TOXICITY VALUE (LD50, LC50, etc):
NA

C. TOXICITY CATEGORY:
IV

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). None **What are they and can they be corrected with additional information?** NA **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? No **Are there any recommendations specific to this study?**
NA

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CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

DEPARTMENT OF PESTICIDE REGULATION

MEDICAL TOXICOLOGY BRANCH

TOXICOLOGY STUDY EVALUATION WORKSHEET
(acute and special studies)

I. STUDY IDENTIFICATION

Active Ingredient: Deltamethrin
Formulated Product Name: K OTHRINE WP 5
Chemical Code #: 3010
SB 950 #: Not assigned
ID: EPA-160696-E
Document #: 51846-091
Record#: 147061
EPA #: NA
Study Type: 814 - Eye irritation
Full Study Title: Primary Eye Irritation Study of K OTHRINE WP 5 in the Rabbit
Company Sponsor: "AGROVET" ROUSSEL UCLAF
Conducting Laboratory: Departement de Toxicologie - Division Scientifique ROUSSEL UCLAF, ROMAINVILLE - FRANCE
Report Date: September 9, 1991
Study Interval: March 12, 1991 to March 19, 1991

II. SUMMARY OF WORKSHEET

A. **STUDY STATUS: Is report complete?** No
Is study acceptable? Yes

- \- **Meets EPA guidelines**
- Yes **Minor variances from guidelines**
- \- **Major variances from guidelines**
- \- **Could be upgraded with additional information (see VI-A)**

- Yes **Has useful data**
- \- **Insufficient data**
- \- **Non EPA validated study**
- **Other**_____

B. **CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?** No **If so, in what area?** NA

C. **ONE LINER-One or two sentence summary of the study:**
51846-091; 147061; Eye Irritation; 814; rabbit; Departement de Toxicologie - Division Scientifique ROUSSEL UCLAF, ROMAINVILLE - FRANCE; 9/9/91; Laboratory Study Number 91/2439/TX; (MRID 439460-02); K OTHRINE WP 5 (4.95% Deltamethrin - a Beige powder); dosed with 100 mg/eye; 6 rabbit eyes tested; mortalities- 0/6; at Day 1 post-dose -Grade 2 (4/6), -1 (2/6) corneal opacity, -Grade 1 (3/6) iritis, -Grade 3 (1/6), -2 (4/6), -1 (1/6) conjunctival irritation; at day 3 post-dose -No eye irritation; Toxicity Category III; study acceptable. (Kahn, 5/28/96)

D. **ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?** Yes

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Charles Kahn — 5/30/96
Associate Pesticide Review Scientist — **Date**

[signature] — 5-31-96
Staff Toxicologist — **Date**

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION AND DURATION OF TREATMENT:
Species: Rabbit
Strain: Albino Hybrid New Zealand White
Source of animals: Elevage Scientifique des Domes, France
Age at start: Approximately 3 months (Weight 2.46 to 2.96 kg)
Route of administration: The test material was instilled into the everted lower lid of the right eye, with the left eye serving as the untreated control.
Vehicle: None reported
Period of treatment: Single

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

	Units (mg/eye)
# Rabbits:	100 / 6

	Mortality
# Dead Rabbits:	0

IV. STUDY DESIGN AND EVALUATION

A. TEST PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).
1. **Test article:** K OTHRINE WP 5 (4.95% Deltamethrin - a Beige powder)
2. **Analysis of dosing material:** Dosed as received
3. **Animal selection:** OK
4. **Animal husbandry:** Individually housed in suspended, stainless steel cages with mesh floors - Temperature 19±3°C and Relative Humidity 30-70%
5. **Mortality:** See III-C
6. **Number of animals:** See III-C
* 7. **Randomization of animals:** Not reported
8. **Dose level selection:** OK
9. **Route of administration:** OK
10. **Exposure conditions:** OK
11. **Controls:** Untreated eyes served as controls
12. **Observation:** Obsevered for eye irritation at 24, 48 and 72 hours post-dose
13. **Necropsies:** Not required
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** OK
19. **Other:** OK

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

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V. RESULTS

A. EFFECTS REPORTED:
Mortalities- 0/6; At Day 1 post-dose -Grade 2 (4/6), -1 (2/6) corneal opacity, -Grade 1 (3/6) iritis, -Grade 3 (1/6), -2 (4/6), -1 (1/6) conjunctival irritation. At day 3 post-dose -No eye irritation.

B. ACUTE TOXICITY VALUE(LD50, LC50, etc):
NA

C. TOXICITY CATEGORY:
III

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). None **What are they and can they be corrected with additional information?** NA **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? No **Are there any recommendations specific to this study?** No

State of California

PESTICIDE EVALUATION
Worker Health & Safety

Date: June 18, 1996

Phone: 324-3930

MRID - 438888-07

Subject: Product Name : Delta 5.0% WP
I.D. No. : EPA-160695E
EPA Reg. No. : 43888-822(IEE) (432-IEE)
Doc. No. : 51846-091
Company : AgrEvo Environmental Health
A.I. : Deltamethrin (5.00%)
Use : Insecticide

Recommendation : Registration must await finalization of the full risk assessment. **The Dermal Sensitization Study is acceptable.**

Summary of Registration Request:

The proposed Section 3 Registration product contains a new active ingredient. The product is intended for formulation into insecticides only. The product carries a Toxicity Category III label warning.

Dermal Sensitization:

Title: Dermal Sensitization Study in Guinea Pigs With Decis 5 % WP Reference: 12 Y 0315 (DPR Rec. No. 147063).

Test Substance: Decis 5 % WP Reference: 12 Y 0315 11/6/90

Test Animals: Male Hartley albino guinea pigs

Method: As a result of the irritation screening studies, the test material was administered as a paste, 50 mg of the test material moistened with 0.05 ml of deionized water for the induction and the challenge applications. The induction applications consisted of the test material mixture applied to each animal in the test group on an adhesive patch and placing the patch on the induction site . The patch was covered with clear polyethylene film and left in place for a six hour exposure. The animals in the test and positive control group were treated on days 1, 3, 6, 8, 10, 13, 15, 17, 20, 22 and 36. On day 36, the challenge dose of the test material mixture was applied to the test group in a manner identical to the previous 10 treatments, with the addition of a second test site placed on the right quadrant of the exposure area. All sites were examined and scored for dermal reactions according to the Draize scoring scale at approximately 24 hours, while skin reactions were made approximately 48 hours after induction treatments 1 and 10, and the challenge treatment. DNCB was utilized as a positive control. None of the animals treated with the test material exhibited irritation during the induction phase of the study.

Summary of Dermal Scores at Challenge:

	TEST MATERIAL 1st INDUCTION	CHALLENGE virgin site	CHALLENGE test	SEVERITY INDEX[1]
erythema				
24 hrs	0/10	0/10	0/10	--
48 hrs	0/10	0/10	0/10	--

[1]Severity Index is equal to the sum of the irritation scores divided by the number of animals

Conclusion: The test material did not elicit a dermal sensitization reaction under conditions of the test. The test material is adequately identified in the inhalation study in the same volume.

Acute Inhalation Data Required: Not at this time (see Medical Toxicology memo dated 5/28/96).

Additional Data/Information Required: Not at this time.

Labeling: The signal word, precautionary statements, health hazards, and protective equipment requirements have been reviewed. The labeling is acceptable.

Richard Bireley
(Assoc. Pest. Review Scientist)

James R. Sanborn
(Staff Toxicologist)

cc: Ann Prichard